IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Kirschner, Mitchell I.	:	
	:	Examiner: Choi, Frank I.
Serial No.: 10/714,156	:	Group Art Unit: 1616
Filed: November 14, 2003	:	Attorney Docket No.: 718689.4
For: NUTRITIONAL FORMULATIONS	:	Customer No.: 027128
	:	Confirmation No.: 2373
Last Office Action: February 9, 2006	:	

DECLARATION PURSUANT TO 37 C.F.R. §1.132

Dear Sir,

The following Affidavit is provided under 37 C.F.R. § 1.132.

I, R. Saul Levinson, declare and say as follows:

1. I earned a Doctorate Degree in Pharmaceutics at the University of Illinois in 1972. I am currently and have been for the last sixteen (16) years been employed at KV Pharmaceutical, and am presently Vice-President of Discovery Research. I have thirty-four (34) years experience in the pharmaceutical industry.

2. I have been involved in the continued development of the subject matter claimed in the above identified U.S. patent application Serial No. 10/714,146, filed November 14, 2003.

3. I have read and I am thoroughly familiar with the Office Action, dated February 9, 2006, with respect to the above identified application and the statement by the Examiner that the application Serial No. 10/714,146 only supports the use of a gelatin capsule, and therefore does not support the use of a tablet formulation.

4. I make this Declaration in support of the patentability of the claims of application Serial No. 10/714,146.

5. From a pharmaceutical standpoint, it is clear that the specification of the application Serial No. 10/714,146 clearly encompasses the use of tablet formulations.

6. The specification of the application Serial No. 10/714,146, at paragraph 95, expressly states that the dosage forms may include ingredients such as binders, adhesives and disintegrants. Binders, adhesives and disintegrants are components utilized in tablet formulations. Binders and adhesives are utilized to hold the tablets together after tablet formation, while disintegrants help the tablets break apart to release the API after tablet ingestion. Binders, adhesives and disintegrants have no useful purpose in, and can even interfere with, gelatin capsule formulations.

7. The specification of the application Serial No. 10/714,146, at paragraph 97, specifically discloses the use of bulking agents include sugar, lactose, gelatin, starch and silicon dioxide. Bulking agents are not only unnecessary, but generally are incompatible with use in a gelatin capsule.

8. The specification of application Serial No. 10/714,146 expressly discloses the use of plasticizers in paragraph 98, including diethyl phthalate, diethyl sebacate, triethyl citrate, cronotic acid, butyl phthalate and dibutyl sebacate. The use of these plasticizers is incompatible with use in a gelatin cap.

9. Therefore, the inclusion of binders, adhesives, disintegrants, bulking agents and plasticizers can only mean the use of tablets is encompassed by the present invention.

10. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above referenced application or any patent issuing thereon.

July 20, 2006

Date

R. Saul Levinson